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EXAMINER	
TOTH, KAREN E	
ART UNIT	**PAPER NUMBER**
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,997	BIBIAN ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-18,21-23,26,27,30-33 and 37-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *38-40* is/are allowed.

6)☒ Claim(s) *1-6,8,9,11-17,21-23,26,27 and 30-33* is/are rejected.

7)☒ Claim(s) *7, 18, 37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

2. Claims 38-40 are objected to because of the following informalities:

Claim 38 recites the limitation "the first reference signal" in line 5 and "the second reference signal" in line 7. There is insufficient antecedent basis for these limitations in the claim.

Claim 39 recites the limitation "the first reference signal" in line 6 and "the second reference signal" in line 11. There is insufficient antecedent basis for these limitations in the claim.

Claim 40 recites the limitation "said wavelet transformation" in line 3 of page 15. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, it will be treated as reading "said time-frequency transformation".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. Claims 1, 2, 5, 7-9, 12-16, 23, 26, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over John (US Patent 6067467) in view of Vierto-Oja (US Patent Application Publication 2003/0055355).

Regarding claim 1, John'467 discloses a method for evaluating CNS depression comprising acquiring a plurality of reference signals that correspond to CNS states (column 2, lines 59-60); selecting a transformation function to apply to at least one signal (column 4, lines 61-62); selecting a statistical function to apply to the results of the transformation function to yield a reference data set that characterizes the patient's CNS state (column 4, lines 63-67); applying the transformation and statistical functions to the reference signals (column 4, lines 61-67); capturing a real-time brain signal from brain activity (column 5, lines 7-9); applying the transformation and statistical functions to the real-time signal (column 5, lines 8-10); comparing the real-time data to the reference data (column 5, lines 9-10); and computing a numerical value representative of the patient's CNS state based upon the comparison (column 3, lines 55-67; column 9, line 48 to column 10, line 10).

The examiner notes that John'467 does not specifically disclose that the transformation function yields coefficients, or the application of a statistical function to the coefficients. However, the application of a transformation function to data inherently yields results that include coefficients, which would subsequently be treated by the statistical function that is applied to the results of the transformation function.

John does not disclose the transformation function used being a wavelet transformation function.

Vierto-Oja teaches a method of evaluating CNS depression comprising performing transformation of signals that correspond to CNS states in order to yield a set of coefficients, such as wavelet transformations (paragraph [0111]), since it is well-

known in the art to use wavelet transformations when evaluating signals corresponding to CNS states, and the use of wavelet functions is more effective at distinguishing between signal components.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of John and used wavelet transformation to yield a set of coefficients from the reference and real-time brain signals, as taught by Vierto-Oja, in order to better distinguish between signal components.

Regarding claim 2, John'467 further discloses that the signals are electroencephalograms (EEG's) (column 2, lines 41-43).

Regarding claim 5, John'467 further discloses that the statistical function is one of group histogram, probability density, standard deviation, or variance (column 4, line 63).

Regarding claim 7, John'467 further discloses that the method is used to measure a patient's level of consciousness (column 3, lines 60-64).

Regarding claim 8, John'467 further discloses that the method is used to measure a patient's level of hypnosis (column 3, lines 42-46).

Regarding claim 9, John'467 further discloses that the method is used to measure the effects of anesthesia upon a patient (column 2, lines 41-43, 57-55, and 64-67).

Regarding claim 12, John'467 further discloses using the method to determine titration and dosage profiles of neurologic and psychoactive compounds and medicaments (column 15, lines 37-57), since anesthesia is a psychoactive drug.

Regarding claim 13, John'467 further discloses that the method may be used to monitor the level of brain ischemia (column 1, lines 53-57; column 3, lines 3-6).

Regarding claim 14, John'467 further discloses that the method may be used to measure neurological activity in a subject (column) to ascertain the effects of neurologic and psychoactive compounds and medicaments on the patient's brain (column 2, lines 41-43, 57-55, and 64-67), since anesthesia is a psychoactive drug.

Regarding claim 15, John'467 further discloses that the CNS states represent distinct states on the continuum between conscious and no brain activity (column 9, lines 52-66).

Regarding claim 16, John'467 further discloses that the distinct CNS states are chosen from among sedation, light anesthesia, deep anesthesia, and no brain activity (column 9, lines 55-65).

Regarding claim 23, John'467 further discloses that the transformation function is a filter with frequency response to yield coefficients of brain activity in a specific frequency band (column 5, lines 49-55).

Regarding claim 26, John'467 further discloses that the comparison is done by computing the correlation between the observed and reference data sets (column 9, lines 19-40).

Regarding claim 32, John'467 discloses a system for evaluating CNS depression comprising a sensor for observing the electrical brain activity of a subject to produce a signal (column 4, lines 24-26; and column 5, lines 7-9); and a digital signal processor for applying a transformation function that yields coefficients to an observed signal (column 4, lines 61-62; column 5, lines 8-10) and applying a statistical function that yields data sets to the observed signal coefficients (column 4, lines 63-67), and for computing a numerical representation of the subject's CNS depression based on the comparison's results (column 3, lines 55-67; column 9, line 48 to column 10, line 10). John does not disclose the applied transformation function being a wavelet transformation.

Vierto-Oja teaches a system for evaluating CNS depression comprising performing transformation of signals that correspond to CNS states in order to yield a set of coefficients, such as wavelet transformations (paragraph [0111]), since it is well-known in the art to use wavelet transformations when evaluating signals corresponding to CNS states.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John and used wavelet transformation to yield a set of coefficients from the observed signals, as taught by Vierto-Oja, since use of wavelet transformation when evaluating signals corresponding to CNS states is well-known in the art.

Regarding claim 33, the computer-operated method of John in view of Vierto-Oja described above in reference to claim 1 inherently has a computer program product

comprising a computer usable medium having computer readable program code embodied within.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over John and Vierto-Oja'355, as applied to claims 1, 2, 5, 7-9, 12-16, 23, 26, and 32-33 above, and further in view of Gevins (US Patent 6947790).

John in view of Vierto-Oja'355 discloses all the elements of the claimed invention, as described above, except for the reference data set coming only from sources other than the patient being observed for the real-time data set.

Gevins teaches a method of analyzing a patient's brain signals by comparing real-time signals to a reference set, where the reference set may be composed entirely of data obtained from a population that does not include the patient in question (column 7, lines 18-27; column 12, lines 47-59), in order to compare the patient's results to an appropriate population to determine if deviations are occurring. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of John and Vierto-Oja'355 and used reference data not from the current subject, as taught by Gevins, in order to determine if the patient is deviating from a norm.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Vierto-Oja'355, as applied to claims 1, 2, 5, 7-9, 12-16, 23, 26, and 32-33 above, and further in view of Tarassenko (US Patent 7031857).

John in view of Vierto-Oja discloses all the elements of the claimed invention, as described above, except for the statistical function being a probability density function and being applied to the two signals at different times. Since the signals of John in view of Vierto-Oja are analyzed as they are captured, the statistical function would therefore inherently be applied to the reference signal at a different time than when it is applied to the observed real-time signal.

Tarassenko teaches a method of analyzing signals from a patient, including brain signals, comprising calculating a probability density function (column 9, lines 26-29 and 66-67), so that the patient's condition may be better indicated to an observer.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Vierto-Oja'355, as applied to claims 1, 2, 5, 7-9, 12-16, 23, 26, and 32-33 above, and further in view of Vierto-Oja'291 (US Patent 6631291).

John'467 discloses all the elements of the current invention, as applied to claim 1, except for using the method to measure neurological activity in order to obtain pharmacodynamic and pharmacokinetic models of neurologic and psychoactive compounds and medicaments.

Viertio-Oja'291 teaches a method of monitoring brain signals (column 2, lines 37-38) and using the data to establish pharmacodynamic and pharmacokinetic models of drug effects (column 11, lines 17-28), so that a patient's treatment is more stringently controlled.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and used the data to establish pharmacodynamic and pharmacokinetic models of the effect of an administered treatment, so that a patient's treatment may be more stringently controlled.

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over John and Vierto-Oja'355, as applied to claims 1, 2, 5, 7-9, 12-16, 23, 26, and 32-33 above, and further in view of McCoy (US Patent 5867118).

John in view of Vierto-Oja'355 discloses all the elements of the claimed invention, as disclosed above, except for the wavelet transformation function being a wavelet packets transform.

McCoy teaches a method of identifying and analyzing patterns in electrical signals, such as EEGs (column 7, lines 20-40) that includes using wavelet transformation and wavelet packet transforms as potential analysis methods, since their use is well-known in the signal processing art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of John in view of Vierto-Oja'355 and used wavelet packet transforms to analyze the captured brain signals, as taught by McCoy, since their use is well known in the signal processing art.

8. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Vierto-Oja, as applied to claims 1, 2, 5, 7-9, 12-16, 23, 26, and 32-33 above, and further in view of Lesser (US Patent Application Publication 2003/0171685).

Regarding claims 22 and 23, John in view of Vierto-Oja discloses using a wavelet transformation to analyze the captured data, but does not provide specifics as to the type of function.

Lesser teaches a method of monitoring a patient's brain signal activity comprising using a wavelet transformation function having joint time and frequency localization properties (paragraphs [0027]-[0028]), where the function may be a wavelet filter (paragraph [0033]), in order to improve the quality of signal processing of the captured signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of John in view of Vierto-Oja and used a wavelet transformation function with joint time and frequency localization properties or a wavelet filter, as taught by Lesser, in order to improve the quality of the signal processing of the captured signals.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over John and Vierto-Oja'355, as applied to claims 1, 2, 5, 7-9, 12-16, 23, 26, and 32-33 above, and further in view of Nordstrom (US Patent Application 2002/0133073).

John and Vierto-Oja'355 disclose all the elements of the claimed invention, as described above, except for using distance metrics to compare the observed signal to the reference signal.

Nordstrom teaches a method of comparing an observed signal to a reference signal using distance metrics (paragraphs [0031], [0055], [0075]), in order to obtain an accurate measure of the relationship between the observed and reference signals.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of John and Vierto-Oja'355 and used distance metrics to determine the relationship between the observed and reference signals, as taught by Nordstrom, in order to obtain an accurate measure of the signals' relationship.

10. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over John and Vierto-Oja'355, as applied to claims 1, 2, 5, 7-9, 12-16, 23, 26, and 32-33 above, and further in view of Lewis (US Patent 5762611).

Regarding claim 30, John in view of Vierto-Oja'355 discloses all the elements of the claimed invention except for the method using a single-channel EEG to provide the signals.

Lewis'611 teaches that a single-channel EEG may be used to provide brain signal data (figure 3; column 6 line 56 to column 7 line 19; column 8, lines 44-48), in order to appropriately match the data capture system to the type of data being captured.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and used an single-channel EEG to capture the data as taught by Lewis'611, in order to appropriately match the data capture system to the type of data being captured.

Regarding claim 31, John in view of Vierto-Oja'355 discloses all the elements of the claimed invention except for the method using a multiple-channel EEG to provide the signals.

Lewis'611 teaches that a multiple-channel EEG may be used to provide brain signal data (column 6 line 56 to column 7 line 19; column 8, lines 44-48), in order to appropriately match the data capture system to the type of data being captured.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of John'467 and used an multiple-channel EEG to capture the data as taught by Lewis'611, in order to appropriately match the data capture system to the type of data being captured.

11. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Vierto-Oja'355 and Vierto-Oja'729 (US Patent Application Publication 2002/0173729).

John discloses a method of extracting information from a brain activity signal comprising obtaining a reference signal that corresponds to a distinct CNS state (column 2, lines 59-60); selecting a transformation function to apply to the signal to yield a set of coefficients (column 4, lines 61-62); selecting a statistical function to apply to the results of the transformation function to yield a reference data set that characterizes the patient's CNS state (column 4, lines 63-67); applying the transformation and statistical functions to the reference signals (column 4, lines 61-67); capturing a real-time brain signal from brain activity (column 5, lines 7-9); applying the transformation

and statistical functions to the real-time signal (column 5, lines 8-10); comparing the real-time data to the reference data (column 5, lines 9-10); and computing a numerical value representative of the patient's CNS state based upon the comparison (column 3, lines 55-67; column 9, line 48 to column 10, line 10). John does not teach using a time-frequency transformation or using a generated reference signal.

Vierto-Oja'355 teaches a method of evaluating CNS depression comprising performing transformation of signals that correspond to CNS states in order to yield a set of coefficients, such as time-frequency transformations (paragraph [0111]), since it is well-known in the art to use time-frequency transformations when evaluating signals corresponding to CNS states.

Vierto-Oja'729 teaches using a generated reference signal when comparing a real-time signal to a reference signal (paragraphs [0057]-[0058]), in order to exert greater control over the quality of the reference signal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of John while using a time-frequency transformation, as taught by Vierto-Oja'355, in order to retain all the information from the signals, and used a generated reference signal, as taught by Vierto-Oja'729, in order to exert greater control over the quality of the reference signal.

Regarding claim 42, John discloses a system comprising a device for observing a subject's brain activity to produce a real-time observed signal (column 4, lines 24-26; and column 5, lines 7-9); a device for applying a transformation function that yields coefficients to the observed signal (column 4, lines 61-62; column 5, lines 8-10) and

applying a statistical function that yields data sets to the observed signal coefficients (column 4, lines 63-67), comparing a reference signal to the real-time data (column 5, lines 9-10), and for computing a numerical representation of the subject's CNS depression based on the comparison's results (column 3, lines 55-67; column 9, line 48 to column 10, line 10). John does not teach a device for generating at reference data set that is representative of a CNS state using an algorithm or the transformation being a time-frequency transformation.

Vierto-Oja'355 teaches evaluating CNS depression comprising performing transformation of signals that correspond to CNS states in order to yield a set of coefficients, such as time-frequency transformations (paragraph [0111]), since it is well-known in the art to use time-frequency transformations when evaluating signals corresponding to CNS states.

Vierto-Oja'729 teaches a device for generating reference signal for use when comparing a real-time signal to a reference signal (paragraphs [0057]-[0058]), in order to exert greater control over the quality of the reference signal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of John with a device for generating a reference signal, as taught by Vierto-Oja'729, in order to exert more control over the reference signal's quality, and using a time-frequency transformation, as taught by Vierto-Oja'355, in order to retain all the data from the signals.

Response to Arguments

12. Applicant's arguments filed 20 February 2007 have been fully considered but they are not persuasive.

13. Regarding Applicant's arguments concerning John, though John does not disclose performing wavelet transformation, Vierto-Oja clearly discloses it as an accepted alternative method of analysis. Though Applicant claims to have obtained unexpected results, Vierto-Oja anticpates these results.

With respect to claim 12, the claimed method does not provide any reason to exclude determining the profiles using historical data; the broadest reasonable interpretation of the claim is a method of determining profiles using any available data. John clearly determines titration and dosage profiles, and just approaches the determination in a different manner.

With respect to claim 13, it is the Examiner's position that only half the cited passage has been considered – that is, John suggests properly administering anesthesia to prevent hypoxia *and* ischemia in the same sentence in the cited passage, though only hypoxia is mentioned in Applicant's arguments. John also clearly discloses monitoring the patient's theta band throughout the document, which may be used to determine ischemia (column 3, lines 3-6).

With respect to claim 33, Applicant argues that because it is not clear whether John uses embedded language or software, the use of a computer program is not inherent. Since Applicant has not defined what is meant by a computer program, either embedded language or software may be considered to anticipate the broadest

reasonable interpretation of the claim, since both would require a computer usable medium with program code.

14. Regarding Applicant's arguments concerning Lesser, it is the Examiner's position that Lesser's provisional applications 60/160328 and 60/201188 provide the priority for anticipating the present application. Applicant's arguments with reference to Lesser's application 09/691051 are moot, as they are not directed to any cited art. Provisional application 60/201188 contains the inventive concepts cited in the present rejections on pages 16-18 of the specification, and clearly anticipates the present application.

In response to applicant's argument that there is no suggestion to combine John and Lesser, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Lesser provides details of a method of signal analysis useful for analyzing brain signals. Applicant's detailed arguments concerning Lesser are, again, directed to art that is not relevant to the present application.

15. In response to applicant's argument that Tarassenko is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed

invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Tarassenko is clearly in the field of the present endeavor and reasonably pertinent, since it may be used to display signals obtained from a patient's brain.

Applicant also argues that the probability density function of Tarassenko is the wrong type of probability density function. Applicant has only claimed "a probability density function," and the broadest reasonable interpretation of such a function would certainly include Tarasenko's function.

16. Applicant has argued that Vierto-Oja'291 is not an obvious modification because there is no relation between entropy and wavelet transformation. The Examiner respectfully disagrees; Vierto-Oja'291 discloses monitoring the complexity of signals obtained from a patient, including such measures as signal entropy. Computation of entropy may involve transfer functions, such as FFT or wavelet transformations, as is generally known in the art and specified in Vierto-Oja'355 (paragraphs [0033]-[0034], [0039], [0044], [0050]-[0051], [0068]-[0069], [0111]).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is well-known in the art to monitor a patient's brain state when administering neurologic and

psychoactive compounds and medicaments, and it would therefore be quite logical to use John in view of Vierto-Oja'355 in combination with Vierto-Oja'291 to do so.

17. Regarding Applicant's arguments concerning Lewis, the invention includes both neuro-magnetometers and EEGs, and the single-channel and multiple-channel references refer to both the types of monitoring devices, as discussed in columns 6 and 7, and figure 3. The specifics of Lewis' method, especially evoked or event-related potentials, are not related to the discussion of the benefits or possibilities of using either single- or multiple-channel measurements.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both John and Lewis are concerned with monitoring and processing signals from a patient's brain.

Allowable Subject Matter

18. Claims 17, 18, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method of claims 17 and 18, including, *inter-alia*, acquiring at least two reference signals for comparison to the real-time signal, where the reference signals correspond to two separate, distinct, and extreme CNS states, such as fully conscious and no brain activity.

The prior art of record fails to anticipate or make obvious the method of claim 37, including, *inter-alia*, using a vector p-norm to computer the difference between real-time and reference brain data sets when determining a level of CNS depression.

19. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the system of claim 38, including, *inter-alia*, a device for acquiring a reference signal corresponding to an awake CNS state from a subject, a device for generating a reference signal corresponding to a CNS state of no brain activity, a device for applying a time-frequency transformation and a statistical function to the two reference signals, a device for observing the brain activity of a subject and acquiring a real-time signal, a device for applying the time-frequency transformation and statistical function to the real-time signal, a device for comparing the data set from the reference signals to the data set from the real-time signal using a vector p-norm, and a device for computing numerical values representative of the patient's CNS depression as a result of the comparison.

The prior art of record fails to anticipate or make obvious the structure of claim 39, including, *inter-alia*, a device for acquiring a first reference signal from a subject that

corresponds to the awake CNS state, a device for applying a time-frequency transformation and statistical function to the first reference signal to produce an awake reference data set, a device for generating a second reference data set using a mathematical formula of Dirac function form where the set is representative of the CNS state of no brain activity, a device for observing a subject's brain activity and obtaining a real-time signal, a device for applying the time-frequency function and statistical function to the real-time signal to produce an observed data set, a device comparing the observed data set to the two reference data sets, and a device for computing a numerical value representative of the patient's level of CNS depression based on the comparison.

The prior art of record fails to anticipate or make obvious the method of claim 40, including, *inter-alia*, generating a first reference signal corresponding to an awake CNS state using a random noise signal generator function, generating a second reference signal that corresponds to a CNS state with no brain activity using a time series of zero values, selecting a time-frequency transformation function that will yield a set of coefficients when applied to one of the reference signals, selecting a statistical function to apply to the coefficients or a subset thereof that will yield a reference data set that characterizes the distinct CNS state corresponding to the reference signal, applying the time-frequency transformation and statistical function to the two reference signals to produce two reference data sets that distinguish between awake and no brain activity CNS states, observing a patient's brain activity and acquiring an observed real-time signal, applying the time-frequency transformation and statistical function to the

observed signal to produce an observed data set, comparing the observed data set to the reference data sets, and computing a numerical value representative of the patient's level of CNS depression.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2006/0217781 to John, which discloses a similar invention.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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